

Food and Drug Administration, HHS

§ 1.285

granted admission under other provisions of the act or other U.S. laws.

[68 FR 59070, Oct. 10, 2003; 69 FR 4851, 4852, Feb. 2, 2004]

§ 1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m), including the requirements of this subpart, is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)).

(b) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act.

(2) Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

[68 FR 59070, Oct. 10, 2003; 69 FR 4852, Feb. 2, 2004]

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under 21 CFR part 1, subpart H?

(a) If an article of food from a foreign manufacturer that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the act and § 1.283 for failure to provide adequate prior notice. The failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415

of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(b) Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food is imported or offered for import from a foreign facility that is not registered as required under section 415 of the act and is placed under hold under section 801(l) of the act, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) *Status and movement of held food.*

(1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of the hold. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated facility.

(d) *Segregation of held foods.* If an article of food that has been placed under hold under section 801(l) of the act is part of a shipment that contains articles that have not been placed under hold, the food under hold may be segregated from the rest of the shipment. This segregation must take place where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) *Costs.* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) *Export after hold.* An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) *No Registration or Request for Review.* If an article of food is placed under hold under section 801(l) of the act and no registration or request for

FDA review is submitted in a timely fashion or export has not occurred in accordance with subsection (f), the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(h) *Food carried by or otherwise accompanying an individual.* If an article of food carried by or otherwise accompanying an individual arriving in the United States is placed under hold under section 801(l) of the act because it is from a foreign facility that is not registered as required under section 415 of the act, 21 U.S.C. 350d, and subpart H, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(i) *Post-refusal and post-hold submissions.* (1) Post-refusal. To resolve the refusal if an article of food is refused under §1.283(a) because the facility is not registered, the facility must be registered and after a registration number has been obtained, you should cancel the prior notice and must resubmit the prior notice in accordance with §1.283(c).

(2) Post-hold. To resolve a hold, if an article of food is held under §1.285(b) because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(i) FDA must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by mail, express courier, fax, or e-mail. The location for receipt of a notification of registration number associated with an article of food under hold is listed at <http://www.fda.gov>—see Food Facility Registration. The notification should include the applicable CBP identifier.

(ii) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(l) of the act.

(j) *FDA review after hold.* (1) If an article of food has been placed under hold

under section 801(l) of the act, a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the prior notice submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Food Facility Registration. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5 calendar days of the hold. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415, it will notify the requestor and CBP that the food is no longer subject to hold under section 801(l) of the act.

(k) *International mail.* If an article of food is that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is held under section 801(l) of the act and there is a return address, the parcel may be returned to sender stamped “No Registration—No Admission Permitted.” If the article is under hold and there is no return address or FDA determines that the article of food is in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender stamped “No Registration—No Admission Permitted” or, if there is no return address, destroy the parcel, at FDA expense.

(1) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), an article of food that has been placed under hold section 801(l) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer subject to hold under section 801(l) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility location until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(m) *Relationship to other admissibility provisions.* A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer under hold under section 801(l) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

[68 FR 59070, Oct. 10, 2003; 69 FR 4852, Feb. 2, 2004]

Subpart J—Establishment, Maintenance, and Availability of Records

SOURCE: 69 FR 71651, Dec. 9, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, “processing” means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the